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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ROANE, AARON F	

ART UNIT	PAPER NUMBER
3769	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/727,151	SWANSON, DAVID K.	
	Examiner	Art Unit	
	Aaron Roane	3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14,17,19,20,32-37,40,42 and 44-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14,17,19,20,32-37,40,42 and 44-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 32-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 32 recites "without the tissue stimulation element piercing the tissue" which is not explicitly supported by the specification, while claims 33 and 34 make similar recitations. In order to provide an examination the examiner interprets this recitation as a recitation that the stimulation elements do not have sharp ends.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims, 14, 17, 19, 20, 32-34, 36, 37, 40-42 and 45-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 32-34 recite "stimulation element too small to form a transmural myocardial lesion" which is indefinite as it is the combination of the size, configuration and energy delivery that determine whether the transmural myocardial lesion is formed and not

merely the size. Therefore this will be interpreted as a functional limition in order to provide an examination.

Claim 37 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 37 recites "a second tissue piercing members", as it is unclear if one or more second members are to be claimed. In order to provide an examination the examiner interprets this recitation as "a second tissue piercing member", that is a single tissue piercing member.

Invocation of 112, sixth paragraph

Claim 32 recites in lines 6-9 "means, associated with the tissue stimulation element, for securing the surgical apparatus to the tissue structure by engaging a single side of the tissue structure and pressing the stimulation element against the single side of the tissue structure," which is interpreted by the examiner as Applicant invoking 112, sixth paragraph. The examiner equates the means for securing as equivalent to the anchor of claim 33.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is

eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/12/2009 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 14, 17, 19, 20, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hess (U.S. Patent 4,144,890) in view of Baker et al. (U.S. Patent 6,228,082).

Regarding claims 14, 17, 32 and 33, Hess discloses a device comprising: a tissue stimulation element, in the form of a stimulation electrode ("a series of spaced helical turns of wire" 21, see col. 2:31- col. 3:35 and figures 1-7) configured to emit stimulation energy that is applied to tissue, wherein a size of the tissue stimulation element is too small to form a transmural myocardial lesion; and an anchor or means for securing (collectively portions defined by 25, 27, 31, 33 and 37 in col. 2:42-55 and figures 1-3 or portions defined by 41-44 in col. 3:9-18 and figures 4-6), associated with the tissue stimulation element, the anchor being configured to secure the surgical apparatus to the tissue by piercing the tissue and pressing the stimulation element against the tissue, see

col. 2:12- col. 3:52 in general. It should be noted the helical electrode 21 of Hess is not responsible for piercing the tissue, but the sharp pointed tip 37 pierces the tip. Hess is silent as to the diameter of the electrode. Baker et al. disclose an electrosurgical device having needle electrodes and teach the "needle electrode is an insulated acupuncture sized needle having a diameter in the range of about 0.05 to about 2.0 mm, preferably less than 1 mm in diameter" (see col. 2:66 - col. 3:2) and further teach a small diameter of 0.05 mm to about 2.0 mm, preferably less than 1.0 mm minimizes tissue trauma (see col. 6:43-45). Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Hess, as taught by Baker et al., to use needle electrodes having a small diameter in the range of 0.05 mm to 2.0 mm in order to minimize tissue trauma.

Regarding claims 19 and 20, Hess discloses that the anchor comprises a flexible carrier (elongated element defined by ends 42 and 42) that is non–linear when in the relaxed state, as it has a u-shaped or cup shaped transverse cross-section, see col. 3:9-18 and figures 4-7.

Regarding claims 42 and 44, the stimulation element ("a series of spaced helical turns of wire" 21, see col. 2:31- col. 3:35 and figures 1-7) of Hess does not have a sharpened distal end.

Claims 14, 32, 34, 36, 37, 40 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rau (U.S. Patent 4,685,466) in view of Franchi (U.S. Patent 5,466,255) in further view of Daddona et al. (U.S. Patent 6,091,975).

Regarding claims 34, 36 and 40, Rau discloses a device comprising: a tissue stimulation element, in the form of a stimulation electrode (needle electrode having pointed tip 1, see col. 4:28-62 and figures 1-6, particularly figures 4 and 5) configured to emit stimulation energy that is applied to tissue (see abstract, col. 3:3-15), wherein a size of the tissue stimulation element is too small to form a transmural myocardial lesion; and a flexible carrier movable ("suction cup" 2, see col. 4:46-52 and figures 4 and 5) between an unstressed state (when no suction/vacuum is applied) and a deflected and stressed state (when suction/vacuum is applied and the tips of the needle electrodes is inserted into the tissue, and since the suction cup is made of a "flexible rubber material," see col. 5:10-12 whenever the suction/vacuum is applied the suction cup is inherent placed in a deflected/stressed state) and including a first end portion (portion of "suction cup" 2 adjacent to "vacuum line" 4, see col. 4:46-52 and figures 4 and 5) that carries the first tissue stimulation element, in the form of a stimulation electrode (needle electrode having pointed tip 1 adjacent to "vacuum line" 4, see col. 4:28-62 and figures 1-6, particularly figures 4 and 5), a second end portion (portion of "suction cup" 2 opposite the "vacuum line" 4, see col. 4:46-52 and figures 4 and 5) that carries the second tissue stimulation element, in the form of a stimulation electrode (needle electrode having pointed tip 1 opposite the "vacuum line" 4, see col. 4:28-62 and figures 1-6, particularly figures 4 and

5) and an interior portion located between the first and second end portions and configured such that the interior portion will be in spaced relation to the tissue surface when the end portions are in contact with the tissue surface and the carrier is in the unstressed state (although this recitation is intended use it is clearly shown in figures 4 and 5). Rau fails to disclose 1) that the interior portion is curved, 2) a tissue engagement device carried by the curved interior portion of the carrier between the first and second tissue stimulation elements and configured to secure the carrier to the tissue surface in the deflected and stressed state and 3) a stimulation element that does not pierce tissue. Franchi discloses a stimulation electrode device and teaches providing the tissue contacting electrically conductive side of the device with a concave surface in order to engage a convex tissue surface and "claws" (9) in order to secure the device to cardiac tissue, see col. 4:15-30 and figures 6-9. Daddona et al. disclose a electrical device for the skin and teach providing the device with a tissue engagement device in the form of a collection of "microprotrusion" barbs (jagged additions to some, i.e. every third electrode 4) in order "to maximize the electrode area while maintaining the small protrusion size necessary for minimally invasive operation" and further secure the device to the skin and as an alternative to pressing the device against the skin by hand wherein the electrode is disposed on the "microprotrusion" barbs, see col. 2, line 18-26 and col. 2 and 3 and figures 1-4. This combination provides a flexible concave suction cup having at least two opposed end stimulation electrodes with a plurality of other stimulation electrodes therebetween wherein some of the interior stimulation electrodes have microprotrusion barbs. Therefore at the time of the invention it would have been obvious to one of

ordinary skill in the art to modify the invention of Rau, as taught by Franchi, to provide the suction cup of Rau with a concave surface in order to engage a convex tissue surface and "claws" in order to secure the device to cardiac tissue, and as further taught by Daddona et al., to provide the device with a tissue engagement device in the form of a collection of "microprotrusion" barbs uniformly distributed on the electrode tips of the interior in order "to maximize the electrode area while maintaining the small protrusion size necessary for minimally invasive operation" and further secure the device to the skin, it should be noted that the stimulation elements taught by Daddona et al. do not pierce tissue but are disposed on the "microprotrusion" barbs that do pierce tissue. It should be noted that the "microprotrusion" barbs (4) of Daddona et al. actually pierce the tissue not the electrodes.

Regarding claims 37, 42 and 44-47, Rau in view of Franchi in further view of Daddona et al. disclose the claimed invention

Regarding claims 48-50, the combination of Rau in view of Franchi in further view of Daddona et al. disclose the claimed invention as it is the "microprotrusion" barbs (4) of Daddona et al. penetrate tissue while the electrodes (14 and 18) are disposed on the "microprotrusion" barbs (4).

Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rau (U.S. Patent 4,685,466) in view of Franchi (U.S. Patent 5,466,255) in further view of Daddona et al. (U.S.

Patent 6,091,975) as applied to claim 34 above, and further in view of Baker et al. (U.S. Patent 6,228,082).

Regarding claim 41, Rau in view of Franchi in further view of Daddona et al. disclose the claimed invention except for the first and second tissue stimulation elements each having a diameter of about 0.5mm to 1.0 mm in diameter. Baker et al. disclose an electrosurgical device having needle electrodes and teach the "needle electrode is an insulated acupuncture sized needle having a diameter in the range of about 0.05 to about 2.0 mm, preferably less than 1 mm in diameter" (see col. 2:66 - col. 3:2) and further teach a small diameter of 0.05 mm to about 2.0 mm, preferably less than 1.0 mm minimizes tissue trauma (see col. 6:43-45). Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Hess, as taught by Baker et al., to use needle electrodes having a small diameter in the range of 0.05 mm to 2.0 mm in order to minimize tissue trauma.

Response to Arguments

Applicant's arguments with respect to claims 14, 17, 19, 20, 32-37, 40 and 42 have been considered but are moot in view of the new ground(s) of rejection. In particular a new interpretation of the Hess patent wherein 37 is no longer part of the stimulation element/electrode but is now part of the anchor (or means for securing). Applicant should be aware that any particular piece of prior art may have multiple interpretations which provide rejections against the presently claimed invention. It is important to keep in mind that the present rejections must

distinguish over any and all interpretation of a particular piece of prior art and/or a combination thereof.

Additionally, the rejection based on Rau combined with Daddona (and other references) al provide a new grounds of rejection wherein it is the "microprotrusion" barbs 94) of Daddona et al. that pierce tissue while the stimulation element(s)/electrode(s) is(are) merely disposed on the "microprotrusion" barbs.

This action is non final.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (571) 272-4771. The examiner can normally be reached on Monday-Thursday 8:30AM-7PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson can be reached on (571) 272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Aaron Roane/
Examiner, Art Unit 3769

/Ahmed M Farah/
Primary Examiner, Art Unit 3769